K120988 JUL 25 2012

510(k) Summary

Date Prepared: March 30, 2012

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Device Name and Classification

Trade Name:	DLP® Single Stage Venous Cannula
	DLP® Right Angle Single Stage Venous Cannula
	DLP® Single Stage Venous Cannula with Right Angle Metal Tip
	DLP® Malleable Single Stage Venous Cannula
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Product Classification:	Class II

Predicate Devices

K842374	Venous Cannula with Bent, Tip Wire
K022272	Malleable Single Stage Venous Cannula
K111972	Malleable Single Stage Venous Cannula with Carmeda BioActive Surface

Device Description

DLP® Single Stage Venous Cannulae devices are used during cardiopulmonary bypass surgical procedures for collecting and directing blood from the right side of the heart via the superior and inferior vena cava into the bypass circuit. These cannulae are comprised of wirewound, kink-resistant Polyvinyl Chloride (PVC) plastisol bodies with a nominal outer diameter of 12Fr to 40Fr (in 2Fr increments) and overall lengths from 12 inches to 15 inches. These cannulae are available in Carmeda® Bioactive Surface coated and uncoated versions. All DLP® Single Stage Venous Cannulae are provided as sterile, nonpyrogenic, disposable, single use devices.

Carmeda® BioActive Surface is a durable, non-leaching end point attached heparin Biosurface that mimics the heparin sulfate naturally found on the vascular endothelium lining the circulatory system. Carmeda® provides thromboresistance, enhanced biocompatibility, and enhanced blood compatibility while reducing platelet activation and adhesion formation.

Indications for Use

These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.

Contraindications

These cannulae are contraindicated for long-term use. Do not use for extended terms such as Ventricular Assist procedures.

Comparison to Predicate Devices

A comparison of the modified product to the currently marketed predicate product (K845045 and K022272) indicate the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same base materials prior to coating
- Same shelf life

A comparison of the modified product and the currently marketed DLP® Single Stage Venous Cannula with Carmeda® BioActive Surface (K111972) indicated the following similarities:

- Same Carmeda® BioActive Surface coating

Conclusion

Medtronic has demonstrated that the modifications made to the DLP® Single Stage Venous Cannula product family described in this submission result in a substantially equivalent device because the fundamental scientific principle, operating principle, design features and intended use are unchanged from the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

Medtronic, Inc.
c/o Ms. Jacqueline A. Hauge
Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K120988
DLP Single Stage Venous Cannula, DLP Right Angle Single Stage Venous Cannula, DLP Single Stage Venous Cannula with Right Angle Metal Tip and DLP Malleable Single Stage Venous Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: June 28, 2012
Received: June 29, 2012

Dear Ms. Hauge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120988

Device Name: DLP® Single Stage Venous Cannula
DLP® Right Angle Single Stage Venous Cannula
DLP® Single Stage Venous Cannula with Right Angle Metal Tip
DLP® Malleable Single Stage Venous Cannula

Indications For Use:

These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours of less.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120988